SMS/2022R00482

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA	:	Hon.. Kevin McNulty
	:	
v.	:	Criminal No. 22-590
	:	
DANIEL HURT	:	18 U.S.C. § 1349

I N F O R M A T I O N

The defendant having waived in open court prosecution by Indictment, the Attorney for the United States, acting under authority conferred by 28 U.S.C. § 515, for the District of New Jersey charges:

COUNT ONE
(Conspiracy to Commit Health Care Fraud)

1. Unless otherwise indicated, at all times relevant to this Information:

The Defendant and Other Individuals and Entities

a. Defendant DANIEL HURT ("defendant HURT") was a resident of Florida. Defendant HURT and other individuals owned, operated, and had financial interests in several clinical laboratories (collectively, the "Subject Laboratories") located in the United States.

b. The "Subject Laboratories" conducted or arranged for a variety of medical tests and included Laboratory-1 (a laboratory with offices in Houston, Texas), Laboratory-2 (a laboratory with offices in Fort Lauderdale, Florida), and

Laboratory-3 (a laboratory with offices in Indio, California, and Fort Lauderdale, Florida).

c. Defendant HURT and others paid kickbacks and bribes to various parties (the "Suppliers") in exchange for referrals and orders for genetic cancer screening tests ("CGX Tests") for beneficiaries of the Medicare Program ("Medicare") and other health care benefit programs without regard to medical necessity.

d. Defendant HURT and others enrolled the Subject Laboratories as Medicare suppliers and were approved to bill Medicare for medically necessary CGX Tests. Pursuant to the requirements described below, the Subject Laboratories were responsible for acknowledging that any claims made to Medicare complied with the relevant laws, regulations, and program instructions. Defendant HURT caused the Subject Laboratories to bill Medicare for medically unnecessary CGX Tests, and the CGX Tests were procured through the payment of kickbacks and bribes.

Background on the Medicare Program and Genetic Testing

e. Medicare was a federal program that provided free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. Medicare was a "health care program" as defined in 18 U.S.C. § 24(b) and a "Federal health care program" as defined in 42 U.S.C. § 1320a-7b(f). The Medicare Part B program was a federally funded supplemental insurance program that provided Medicare insurance benefits for individuals aged 65 or

older, and for certain individuals who were disabled. The Medicare Part B program paid for various medical services for beneficiaries, including CGX Tests.

f. Genetic tests were laboratory tests designed to identify specific inherited mutations in a patient's genes. These genetic variations affected a patient's risk of developing certain diseases or how the patient responded to medications. CGX Tests were genetic tests related to a patient's hereditary predisposition for cancer.

g. To conduct a genetic test, a laboratory must obtain a DNA sample from the patient. Such samples were typically obtained from the patient's saliva by using a cheek (buccal) swab to collect sufficient cells to provide a genetic profile. The DNA sample was then submitted to the laboratory for analysis, such as CGX Tests.

h. If the patient had insurance, the laboratory would typically submit a claim for reimbursement for the test to the patient's insurance carrier. The claims for payment for CGX Tests sometimes exceeded $10,000, while reimbursement rates for CGX Tests sometimes exceeded approximately $8,000 per test.

i. Medicare excluded from coverage diagnostic genetic tests "that are not reasonable and necessary . . . [f]or the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 C.F.R. § 411.15(k)(1). To be considered "reasonable and necessary," Medicare rules required that genetic testing "be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a

beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a). "Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." *Id.*

j. In order for a healthcare provider to bill Medicare for services rendered, it had to enroll with Medicare as a Medicare provider or "Supplier." For example, in order to bill Medicare for a CGX Test, Coronavirus Test, or RPP Test, a clinical laboratory was first required to complete and submit a Form CMS-855B, the Medicare Enrollment Application for "Clinics/Group Practices and Certain Other Suppliers."

k. As provided in the Form CMS-855B, in order to enroll with Medicare, a supplier of healthcare services such as a clinical laboratory had to, among other things, certify the following: (1) the supplier understood that any deliberate omission, misrepresentation, or falsification of any information on the Form CMS-855B could be punished by criminal, civil, or administrative penalties; (2) the supplier agreed to abide by applicable Medicare laws, regulations, and program instructions, such as, but not limited to, the federal anti-kickback statute (42 U.S.C. § 1320a-1b(b)) ("AKS"); (4) the supplier understood that payment of a claim by Medicare was conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions; and (5) the supplier had to refrain from knowingly presenting or causing to present a false or fraudulent claim for payment by

Medicare and submitting claims with deliberate ignorance or reckless disregard of their truth or falsity.

l. Medicare-authorized suppliers of healthcare services, such as clinical laboratories, could only submit claims to Medicare for reasonable and medically necessary services. Medicare would not reimburse claims for services that it knew were neither reasonable nor medically necessary. Likewise, Medicare would not reimburse claims for services that it knew were procured through kickbacks or bribes. Such claims were deemed false and fraudulent because they violated Medicare laws, regulations, and program instructions, as well as violated federal criminal law. For example, where a CGX Test was procured through the payment of a kickback in violation of the AKS, a claim to Medicare for reimbursement for that test was fraudulent. By implementing these restrictions, Medicare aimed to preserve its resources, which were largely funded by United States taxpayers, for those elderly and other qualifying beneficiaries who had a need for genuine medical services.

The Conspiracy

2. From at least as early as in or about January 2019 through in or about October 2021, in the District of New Jersey, and elsewhere, defendant

DANIEL HURT

did knowingly and intentionally conspire and agree with others to knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud a health care benefit program and to obtain, by means of false and fraudulent pretenses, representations, and promises, any of the money owned by, and

under the custody and control of, a health care benefit program, as defined by 18 U.S.C. § 24(b), in connection with the delivery of or payment for health care benefits, items and services, contrary to Title 18, United States Code, Section 1347.

Goal of the Conspiracy

3. The goal of the conspiracy was for defendant HURT and others to profit by submitting or causing the submission of false and fraudulent claims to Medicare.

Manner and Means of the Conspiracy

4. The manner and means by which defendant HURT and others sought to accomplish the goal of the conspiracy included, among other things, the following:

a. From at least as early as in or around January 2019, defendant HURT (through the Subject Laboratories) and others entered into kickback agreements with individuals who operated the Suppliers that targeted Medicare beneficiaries for CGX Tests. Under these agreements, defendant HURT and others paid kickbacks to the Suppliers for each Medicare beneficiary the Suppliers referred to defendant HURT and others if the beneficiaries ultimately received CGX Tests from the Subject Laboratories, without regard for medical necessity. The Subject Laboratories submitted claims for payment to Medicare for these CGX Tests. Medicare reimbursed the Subject Laboratories without

knowing that the services were not medically necessary or were procured through the payment of kickbacks.

b. Generally speaking, in order to generate referrals and orders for CGX Tests, Suppliers used a variety of methods, including making cold calls, using targeted Internet advertisements, and making in-person solicitations for various medical services to elderly Medicare beneficiaries across the United States, including New Jersey. Through the Suppliers, targeted beneficiaries were questioned to determine whether they met certain eligibility requirements for the relevant test. Once the Suppliers identified an eligible beneficiary, the Suppliers worked with a network of telemedicine health care providers to generate prescriptions for CGX Tests. In general, those health care providers were not treating the beneficiaries for any symptoms or conditions, but instead intended to provide those pre-screened beneficiaries with prescriptions for CGX Tests regardless of medical necessity.

c. Once the Suppliers obtained prescriptions—and sometimes before the Suppliers obtained prescriptions—the Suppliers sent testing kits to the beneficiaries. Beneficiaries then completed the buccal swab or other testing mechanism contained in the kit and returned it to the Suppliers or Subject Laboratories. Defendant HURT knew that the Suppliers were not treating beneficiaries for a specific medical problem or using the CGX Test results in the management of the beneficiary's specific medical problem.

d. Ultimately, defendant HURT (through the Subject Laboratories) electronically submitted or caused the electronic submission of

fraudulent claims to Medicare and other health care benefit programs for payment for each of the CGX Tests. The following nine (9) examples show HURT's participation in the scheme:

1. On or about October 14, 2021, defendant HURT (through the Subject Laboratories) submitted or caused to be submitted a fraudulent claim to Medicare with respect to Patient A, for which Medicare paid approximately $6,689.52. Patient A was solicited by telephone and told she/he qualified for free genetic testing based on Patient A's answers to a series of questions about his/her family history. The genetic test was not ordered by Patient A's treating physicians. Patient A has never been treated by or spoken with the referring provider for the CGX Test. When she/he attempted to contact the Subject Laboratory for consultation on the results of her/his genetic test, no one was available to discuss the results. The test results were not used in the management of Patient A's specific medical care.

2. On or about March 10, 2021, defendant HURT (through the Subject Laboratories) submitted or caused to be submitted a fraudulent claim to Medicare with respect to Patient B, for which Medicare paid approximately $6,288.73. Patient B was solicited by telephone and told that there was a new Medicare program that provides cancer genetic testing at no cost to him/her. The genetic test was not ordered by Patient B's treating physicians. Patient B has never been treated by or spoken with the referring provider for the CGX Test. Patient B completed the test kit that was sent to him/her by mail, but to date, has not received the test results.

3. On or about July 2, 2020, defendant HURT (through the Subject Laboratories) submitted or caused to be submitted a fraudulent claim to Medicare with respect to Patient C, for which Medicare paid approximately $6,288.73. Patient C was solicited by telephone and agreed to receive the test kit under the belief that his/her nephrologist had ordered the test. However, the test was not ordered by Patient C's nephrologist or any of her/his treating physicians. Patient C has never been treated by or spoken with the referring physician for the CGX Test. Patient C completed the test kit that was sent to him/her by mail, but to date, has not received the test results.

4. On or about March 17, 2021, defendant HURT (through the Subject Laboratories) submitted or caused to be submitted a fraudulent claim to Medicare with respect to Patient D, for which Medicare paid approximately $10,100.38. Patient D was solicited by telephone and offered free genetic testing. The test was not ordered by Patient D 's treating physicians. Patient D has never been treated by or spoken to the referring provider for the CGX Test, and the test results have not been used in the management of Patient D's specific medical care.

5. On or about October 14, 2021, defendant HURT (through the Subject Laboratories) submitted or caused to be submitted a fraudulent claim to Medicare with respect to Patient E, for which Medicare paid approximately $7,241.32. Patient E was solicited by telephone and offered free genetic testing. The test was not ordered by Patient E's treating physicians. Patient E has never been treated by or spoken to the referring provider for the CGX Test, and the test results have not been used in the management of Patient E's specific medical care.

6. On or about October 20, 2020, defendant HURT (through the Subject Laboratories) submitted or caused to be submitted fraudulent claims to Medicare with respect to Patient F, for which Medicare paid approximately $9,429.89. Patient F does not recall participating in any genetic testing. Patient F has never been treated by or spoken to the referring provider for the CGX Test. Patient F does not recall receiving any test results for genetic testing.

7. On or before September 3, 2019, defendant HURT (through the Subject Laboratories) submitted or caused to be submitted fraudulent claims to Medicare with respect to Patient G, for which Medicare paid approximately $4,684. Patient G does not recall participating in any genetic testing. She/he has not swabbed his/her mouth, nor has anyone swabbed his/her mouth for genetic testing. She/he has never been treated by or spoken to the referring provider. Patient G does not recall receiving any test results for genetic testing.

8. On or before September 26, 2019, defendant HURT (through the Subject Laboratories) submitted or caused to be submitted fraudulent claims to Medicare with respect to Patient H, for which Medicare paid approximately $4,684. Patient H was solicited at a "Lifestyles after 50" event and was told that there was a Medicare program that provides cancer genetic testing at no cost to her/him. The genetic test was not ordered by Patient H's treating

physician. Patient H has never been treated by or spoken with the referring provider for the CGX Test. Patient H received his/her test results, but was not contacted by anyone to explain the results and was not offered a consult to interpret the results. Patient H's primary care physician has never discussed the genetic test results with him/her.

9. On or before October 17, 2019, defendant HURT (through the Subject Laboratories) submitted or caused to be submitted a fraudulent claim to Medicare with respect to Patient I, for which Medicare paid approximately $4,684. Patient I was solicited by text message and telephone offering free genetic testing. The genetic test was not ordered by Patient I's treating physicians. Patient I has never been treated by or spoken with the referring provider for the CGX Test. Patient I received notices that she/he did not provide enough saliva in the samples for genetic testing. Patient I did not return a second saliva sample and did not receive any test results. Despite this, Patient I's genetic tests were billed to Medicare.

e. Between in or around January 2019 and October 2021, defendant HURT and others (through the Subject Laboratories) submitted or caused to be submitted approximately 350,000 claims to Medicare, including approximately 8,700 claims for beneficiaries residing in New Jersey.

f. Defendant HURT (through the Subject Laboratories) paid kickbacks to Suppliers for each CGX Test that was billed to Medicare and other health care benefit programs.

g. To conceal the payments of bribes in exchange for referral of patients for CGX Tests that were not medically necessary, defendant HURT (through the Subject Laboratories) and the Suppliers entered into sham contracts in order to make it appear that the Suppliers was engaged in, and being paid for, legitimate marketing and referral services for the Subject Laboratories (the "CGX Agreements"). The CGX Agreements provided, among

other things, that the Subject Laboratories would pay the Suppliers based on the hours and expenses incurred or on a flat-rate basis. In reality, defendant HURT and the Suppliers understood that payments were on a per-test basis. Defendant HURT and others knew that the claims to Medicare and other health care benefit programs for each of the CGX Tests were fraudulent because the CGX tests were (i) medically unnecessary; (ii) approved by providers not treating the beneficiary; and (iii) procured through the payment of kickbacks and bribes and therefore not eligible for federal reimbursement.

h. As a result of defendant HURT's participation in the health care fraud scheme, from at least as early as in or about January 2019 through in or about October 2021, Medicare paid the Subject Laboratories at least approximately $53,319,506 for CGX Test claims that were the product of the illicit scheme. Defendant HURT received at least approximately $26,883,480.70 from these Medicare reimbursements.

All in violation of Title 18, United States Code, Section 1349.

FORFEITURE ALLEGATIONS

1. Upon conviction of the offense alleged in this Information, defendant HURT shall forfeit to the United States, pursuant to 18 U.S.C. § 982(a)(7), all property, real or personal, that constitutes or is derived, directly and indirectly, from gross proceeds traceable to the commission of the offense (as defined in 18 U.S.C. § 24) alleged in this Information, which was at least approximately $26,883,480.70.

SUBSTITUTE ASSETS PROVISION
(Applicable to All Forfeiture Allegations)

2. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third person;

(c) has been placed beyond the jurisdiction of the Court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be subdivided without difficulty;

the United States shall be entitled to forfeiture of substitute property, pursuant to 21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 982(b).

LEE M. CORTES, JR.
Attorney for the United States,
Acting Under Authority Conferred
By 28 U.S.C. § 515